SEP 2 2 2004

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS:
Stryker® Leibinger Skeletal Anchoring System

K041651

General Information

Proprietary Name:	Stryker® Leibinger Skeletal Anchoring System
Common Name:	Endosseous Implant
Proposed Regulatory Class:	Class III
Device Classification:	DZE (872.3640)
Submitter:	Stryker Leibinger 4100 East Milham Avenue Kalamazoo, MI 49001 269-323-4226
Submitter's Registration #:	1811755
Manufacturer's Registration #:	8010177
Contact Person:	Wade T. Rutkoskie Associate Manager RA QA Phone: 269-323-4226 Fax: 269-323-4215
Summary Preparation Date:	June 4, 2004

Intended Use

The Stryker® Leibinger Universal Skeletal Anchoring System is a plating system intended to be placed in the mouth for use as an anchor in orthodontic procedures.

Substantial Equivalency Information

The Stryker® Leibinger Skeletal Anchoring System is substantially equivalent to legally marketed K033483 KLS-Martin Ortho Anchorage System, K022185 Universal CMF System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 30 2004

Mr. Wade T. Rutkoskie
Regulatory Affairs Associate
Stryker Instruments
4100 East Milham Avenue
Kalamazoo, Michigan 49024

Re: K041651
Trade/Device Name: Stryker Leibinger Skeletal Anchoring System
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: DZE
Dated: September 21, 2004
Received: September 23, 2004

Dear Mr. Rutkoskie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

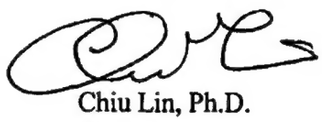
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041651

Device Name: Stryker Leibinger Skeletal Anchoring System

Indications For Use:

The Stryker Leibinger Skeletal Anchoring System is a plating system intended to be placed in the mouth, for use as an anchor in orthodontic procedures.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert S Beddow DDS for Dr. Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K041651